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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,710	07/27/2005	Kamel Khalili	06056-0309US1	4632
23973 7590 10/08/2008 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996				
EXAMINER				
HUFF, SHEELA JITENDRA				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
10/08/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,710

Applicant(s)

KHALILI, KAMEL

Examiner

Sheela J. Huff

Art Unit

1643

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 8/5/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed on 8/5/08 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-12 and 18-25 are pending.

Both new matter rejections are withdrawn in view of applicant's amendment/argument.

The rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's argument.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 18-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The reasons for this rejection are of record in the paper mailed 8/17/07.

Applicant reiterates arguments from the previous response. These have been addressed in the previous office action.

Applicant argues that "correlation" "refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use" and thus the Office must consider the correlation between the *in vitro* assay and the claimed method of use. The Examiner has clearly done this. The rejection mailed on 8/17/07 clearly provided several pieces of art to show that skilled artisans do not readily correlate *in vitro* conditions to *in vivo* conditions. As stated in the rejection, Gura clearly states that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, of reference). Jain also states that therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treat of common solid tumors (p. 65 of reference). These references clearly show that it is well known in the art that *in vitro* conditions do not correlate to *in vivo* conditions. Thus, the Examiner has clearly weighed the evidence of what applicant has provided in the specification to what is accepted in the state of the art.

Applicant again cites Zhao and Yoshida as showing correlation between the human U87MG glioblastoma cell line used in the specification and *in vivo* use. The Zhao reference provides only *in vitro* data and as discussed above, one skilled in the art does not readily correlate *in vitro* data to *in vivo* use. This reference does use the aforementioned cell line, and clearly states that the "drug may be considered for *in vivo* testing". Zhao, taken in view of Gura, means that skilled artisans would not consider

this drug to be useful in vivo, absent objective evidence. Zhao does not show or even mention that drugs that have been tested in the aforementioned cell line have been able to inhibit cell growth in vivo. Yoshida et al does not remedy this deficiency.

Applicant argues that *In Re Brana* still applies and that the examiner has not distinguished the instant case from *Brana*. As stated in the last response, the cell lines used in the case were recognized by NCI (ie art recognized) as being correlatable to in vivo use. There is no objective evidence of record to show that the U87MG glioblastoma cell line used by applicant, even in view of Zhao et al and Yoshida et al (discussed above), can be correlated to in vivo use.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims refer to "the JCV agnoprotein". There is no antecedent basis for this terminology in the claim from which it depends.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/
Primary Examiner
Art Unit 1643

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